

REMARKS

In the Final Office Action mailed on March 15, 2007, the Examiner objected to claim 5, rejected claims 5-12, and indicated claims 13 and 15-34 as allowed. Reconsideration of the application in view of the remarks set forth below is respectfully requested.

Claim Objection

In the Final Office Action, the Examiner objected to claim 5 because the Examiner asserted that the first “the” in line 9 should be deleted. Applicants respectfully traverse this objection. The first “the” in line 9 is provided because the terms “first and second digital signals” have antecedent basis in line 5. Accordingly, Applicants request that the Examiner withdraw the objection to claim 5.

Rejection Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 5-9, 11 and 12 under 35 U.S.C. § 103(a) as being obvious over Diab et al., U.S. Patent No. 5,632,272 (hereafter “the Diab reference”) in view of Zhorian et al., U.S. Patent No. 5,524,631 (hereafter “the Zhorian reference”), and rejected claim 10 as being obvious over the Diab reference in view of the Zhorian reference as applied to claim 9, and further in view of Courtin et al., U.S. Patent No. 3,916,878 (hereafter “the Courtin reference”). Applicants respectfully traverse the rejections.

The burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (B.P.A.I. 1979). To establish *prima facie* obviousness of a claimed invention, *all* the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (emphasis added).

Embodiments of the present invention are directed to a pulse oximeter that uses multiple different calculation techniques. *See* Application, page 6. In other words, present embodiments calculate saturation values by processing the same input data through different algorithms. *See id.* An example of this is illustrated in FIG. 1A of the application, wherein oximetry data (IR & RED) is shown passing into a saturation calculation algorithm (box 50) in two parallel data streams. Each data stream includes the same information, but the information is treated differently to provide two differently calculated saturation values. For example, a first saturation value may be calculated using a harmonic filter 17 and a Kalman-filter-based cardiac gated averaging (CGA) technique 16 to obtain a data stream, and a second saturation value may be calculated based on raw data received directly from a band pass filter. *See* Application, pages 6 and 8. Once the two saturation values are separately determined, the calculation with the “best” or most accurate output may be chosen according to confidence levels (box 26) associated with each calculation. *See* Application, page 8. That is, present embodiments may *arbitrate* between the two values based on a set of arbitration rules. *See* Application, page 6. For example, one calculated saturation value may have been filtered to reduce noise effects and another calculated saturation value may have been determined based on an assumption that a relatively noise-free

signal was utilized. Each of these calculations may have a different confidence value associated with it based on the method of determination. *See* Application, page 6, 9, and 34. Accordingly, in one embodiment, if no significant noise was present in the signal, the confidence level of the calculation that assumes a noise-free signal may be higher than the filtered value and, thus, may be selected as a representative saturation value.

Accordingly, independent claim 5 recites, *inter alia*, “a best rate module configured to *arbitrate* between the first and second pulse rates based on a pulse rate confidence associated with the first and second pulse rate signals to select a best pulse rate.” (Emphasis added).

Applicants assert that Diab fails to teach a best rate module configured to *arbitrate* between the first and second pulse rates based on a confidence associated with the related signals, as recited in claim 5. Indeed, as will be discussed in detail below, during the prosecution of a related application, the Primary Examiner for the present application, Examiner Winakur, painstakingly evaluated the Diab reference and concluded, as have the Applicants, that it does not disclose *arbitrating* between two first and second pulse rates.

The present application is a continuation of U.S. App. No. 10/072,589 (hereafter “the ‘589 application”), which eventually issued as U.S. Patent No. 6,836,679. During the prosecution of the ‘589 application, the teachings of the Diab reference were specifically and thoroughly addressed in a Notice of Allowability mailed June 3, 2004 and signed by Eric Winakur, the Primary Examiner for the present application. A complete copy of the Notice of

Allowability is attached hereto as Exhibit A. It should be noted that in the Notice of

Allowability, the Diab reference is referred to as “the ‘272 patent.” Specifically, the Examiner stated the following, *inter alia*:

The Examiner evaluated the specification and claims of the ‘272 patent and the Examiner concluded that *the ‘272 patent does not teach or suggest* arbitrating between first and second oxygen saturation values to find the best oxygen saturation or *arbitrating between first and second pulse rates to find the best pulse rate*. In particular, the ‘272 patent teaches a traditional seed saturation calculation and five bin seed saturation calculations but *there is no arbitration between them*. (Fig. 17 of ‘272). The ‘272 patent also discloses comparing the bin seed saturations with saturation values of selected peaks in each data bin but this is only an intermediary step for the final calculation of oxygen saturation. (column 46, lines 28-60 of ‘272). The ‘272 patent does not teach or suggest that bin seed saturations or the saturation values of the selected peaks in each bin are oxygen saturation values that are compared so that the best one is selected for output. Rather, the ‘272 patent teaches that these intermediary calculations are used to determine only one oxygen saturation value.

Exhibit A, page 3 (emphasis added).

One thing is certain: the teachings of the Diab reference have not changed since June 3, 2004, when Examiner Winakur analyzed the Diab reference and proclaimed that it did *not* teach *arbitrating* between two pulse rates. Consequently, it would be incongruous for the present Examiner, in an Official Action *signed* by Examiner Winakur, to adopt an interpretation *contrary* to the previous interpretation. Indeed, Applicants’ previous arguments regarding the Diab reference are believed to be correct and in harmony with conclusions espoused by Examiner Winakur over three years ago. Hence, Applicants respectfully submit that Examiner Berhanu has misinterpreted the Diab reference and improperly rejected the present claims based on this

misinterpretation. Accordingly, Applicants respectfully request withdrawal of all outstanding rejections based on the Diab reference and allowance of all pending claims.

Allowable Subject Matter

In the Final Office Action, the Examiner indicated claims 13 and 15-34 are allowed. Applicants would like to thank the Examiner for indicating the allowed claims.

Conclusion

If the Examiner believes that a telephonic interview will help speed this application toward issuance, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date: June 15, 2007


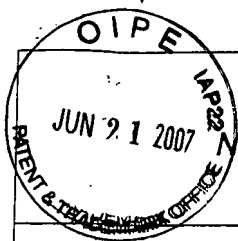

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EXHIBIT A



Notice of Allowability

Application No.

10/072,589

Examiner

Matthew J Kremer

Applicant(s)

BAKER ET AL.

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to a Request for Continued Examination filed on 3/15/2004.
2. ☒ The allowed claim(s) is/are 18-28,31,34 and 37-60.
3. ☒ The drawings filed on 05 February 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 03152004; 04162004
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S COMMENT

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/15/2004 has been entered.

Inventorship

2. In view of the papers filed 2/23/2004, the inventorship in this nonprovisional application has been changed by the deletion of Thomas J. Yorkey.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Reasons For Allowance

3. The following is an examiner's statement of reasons for allowance. The Examiner considered the submissions of the Information Disclosure Statement (IDS)

filed on 4/16/2004 and 3/15/2004. The Examiner does not believe that any of the cited references on those IDS's read on the claims of the present application. Again, the Examiner would like to note the submission of U.S. Patent 6,157,850 to Diab et al. (cited by Applicant). The scope of the claim language of the '850 patent was not considered relevant during the Examination of the current Application since the patent application of the '850 patent was submitted after the domestic priority of the present application. The specification of the '850 patent was identical to its parent (U.S. Patent 5,632,272), which was submitted before the priority of the present application. The Examiner evaluated the specification and claims of the '272 patent and the Examiner concluded that the '272 patent does not teach or suggest arbitrating between first and second oxygen saturation values to find the best oxygen saturation or arbitrating between first and second pulse rates to find the best pulse rate. In particular, the '272 patent teaches a traditional seed saturation calculation and five bin seed saturation calculations but there is no arbitration between them. (Fig. 17 of '272). The '272 patent also discloses comparing the bin seed saturations with saturation values of selected peaks in each data bin but this is only an intermediary step for the final calculation of oxygen saturation. (column 46, lines 28-60 of '272). The '272 patent does not teach or suggest that bin seed saturations or the saturation values of the selected peaks in each bin are oxygen saturation values that are compared so that the best one is selected for output. Rather, the '272 patent teaches that these intermediary calculations are used to determine only one oxygen saturation value.

As to the testimony from the litigation between Masimo and Nellcor (cited in the IDS filed on 4/16/2004), the Examiner believes that the testimony is not relevant for the following reasons. First, the issue at hand was the infringement of a Nellcor device on the patent claims held by Masimo. A patent claim in a first patent (first patent claim) can be deemed novel even though it may infringe on a claim in a second patent (second patent claim) if all the claim elements of the second patent claim are found in the first patent claim. In other words, the novelty of any additional claim elements in the first patent claim does not protect the first patent from infringing the second patent. Second, the testimony by the parties in the case is not considered prior art since all testimony was given after the domestic priority date of the present application. Third, all statements made by the parties in the case do not persuade the Examiner from the opinion that claims of the present application are allowable in view of the '850 or '272 patent for the reasons stated above. Finally, the parties in the case cited no prior art in which the Examiner would reject the claims in the present case.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew Kremer
Assistant Examiner
Art Unit 3736



ERIC F. WINAKUR
PRIMARY EXAMINER